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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/993,667 | 11/14/2001 | Avi J. Ashkenazi | P2730PIC4 | 3324 |

35489 7590 04/20/2004

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,667

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/28/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendments filed 11/14/01 and 9/03/02 have been entered.

Specification

5 The disclosure is objected to because of the following informalities: on p. 548, line 19, "samples" should be "sample".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 119, 124 and dependent claims 120-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Claims 119 and 124 are indefinite because claim 119 recites "binds" and claim 124 recites "specifically binds". Absent a definition of "specific binding" it is not clear what the difference between the two claims is and what each claim is meant to encompass, given that antibody binding is determined by the variable regions structure and is a "specific" event.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

25 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 119-124 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

30 The claims are drawn to an antibody that binds SEQ ID NO:33 (PRO290). While the disclosed nucleic acid of SEQ ID NO:33, which encodes the protein called PRO290, has utility as a screening probe to detect squama cell-type lung carcinomas (pages 550, TABLE 9A), the

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polypeptide and antibody that binds the polypeptide have no such utility. There is no specific or substantial function attributable to the polypeptide, and even though it is stated that PRO290 is most related to FAN and beige proteins (p. 410, line 18), a shared identity of less than 20% is too low to reliably extrapolate function from structure (see SEQUENCE COMPARISON US 5,952,223). Further, the function of these proteins was unclear in the prior art. The prior art does not provide sufficient information to allow the skilled artisan to use PRO290 without significant further research. If the protein does not have utility, then the antibody that binds the protein has no utility.

Even though the nucleic acid has utility as a probe for screening for lung tumor cells, the encoded polypeptide has no such utility since there is no reason to suspect that there is alteration of polypeptide sequence or amount in lung tumor *versus* normal tissue. Even if the DNA has utility as a lung tumor marker, the encoded protein does not have utility because it is not known what the protein does or if the level of PRO290 protein in lung tumors corresponds to nucleic acid transcript level, *i.e.*, if an increased gene amplification in lung tumors corresponds to an increased amount of expressed protein. If the antigen does not have utility, the antibody that binds that antigen likewise does not have utility. It does not necessary follow that an increase in gene copy number results in increased gene expression and increased protein expression, such that the polypeptide would be useful diagnostically or as a target for cancer drug development. For example, Pennica et al. (1998, PNAS USA 95, p.14722, second paragraph) teach that:

An analysis of WISP-1 gene amplification and expression in human colon tumors showed a correlation between DNA amplification and overexpression, whereas overexpression of WISP-3 RNA was seen in the absence of DNA amplification. In contrast, WISP-2 DNA was amplified in colon tumors, but its mRNA expression was significantly reduced in the majority of tumors compared with expression in normal colonic mucosa from the same patient.

Additionally, Hayes et al. (Electrophoresis 19 :1862-1871, 1998) studied 80 proteins relatively homogenous in half-life and expression level, and found no strong correlation between protein and transcript levels; for some genes, equivalent mRNA levels translated into protein abundances which varied by more than 50-fold. It was concluded that the protein levels cannot be accurately predicted from the level of the corresponding mRNA transcript (p. 1863, second paragraph, and Figure 1). Therefore, because it cannot be concluded that PRO290 is associated with formation or growth of lung tumor or is useful itself as a diagnostic marker for lung cancer, the encoded

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protein does not have utility. Significant further research would be required to find out what the protein does and if and how it is linked to lung cancer.

For these reasons, there is no substantial and specific utility for the claimed antibody.

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Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15

Claims 119-124 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

20

The specification provides little beyond structural data and potential activities of the PRO290 polypeptide without guidance about which specific activities one could reasonably expect the polypeptide to possess as discussed above. It would require undue experimentation to use the claimed antibody. For these reasons which include lack of information on the relationship of structure to function of PRO290, paucity of information in the prior art, limited working example, and lack of guidance for use provided in the specification, it would require undue experimentation to use the claimed nucleic acid commensurate in scope with the claims.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant
5 *does* submit a paper by fax, the original signed copy should be retained by the applicant or
applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to
avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.

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Patent Examiner, Art Unit 1646

April 15, 2004